Patient safety initiatives in obstetrics: A Rapid Review
Appendices

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Appendix A – Protocol

METHODS:

To answer the research question "What are the available randomised clinical trials that evaluate patient safety interventions in obstetrical care?" we propose doing a rapid scoping review. Below is our proposed method for this rapid scoping review.

Scoping reviews

A scoping review aims to "map the literature on a particular topic or research area and provide an opportunity to identify key concepts, gaps in the research; and types and sources of evidence to inform practice, policymaking, and research".[1] A scoping review essentially follows the same steps of a systematic review recommended by the Cochrane Collaboration,[2] except the quality of included studies is not appraised because the purpose is to map out the literature and identify areas to conduct future systematic reviews.

Rapid reviews

Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner.[3] Depending on the scope and timelines, rapid reviews will streamline some of the processes recommended by the Cochrane Collaboration, such as only 1 reviewer screening the literature search results, abstracting data, and appraising quality. A meta-analysis generally is not conducted for a rapid review.

We have conducted rapid scoping reviews for the World Health Organization (in 2011) and Toronto-Central-Local Health Integrated Network (in 2012) and the lead scientist (Dr. Tricco) on this proposal is interested in studying and improving scoping review and rapid review methods.

Search Strategy

We will use the methodologically rigorous rapid scoping review approach. We will conduct a systematic search across the following electronic databases from inception onwards: MEDLINE (OVID interface), EMBASE (OVID interface), LexisNexis Academic, and the Legal Scholarship Network. The general search terms included those related to obstetrics and patient safety interventions. In order to limit the search, we focused on randomised clinical trials and publications in English from 2004 onwards.

A search conducted on August 13, 2015 of MEDLINE and EMBASE using the defined terms retrieved approximately 5000 citations. We aim to also search to legal databases after we further refine the search strategy with input from the investigators and in consultation with our experienced information specialist. The search strategy has already been peer reviewed by another librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist (see PubMed ID: 19230612). After this exercise, the search strategy was finalised. The information specialist will execute all final searches, export the results into EndNote, and remove all

duplicates from the search results. The results will then be uploaded to Synthesi.SR (http://knowledgetranslation.ca/sysrev/login.php), proprietary software available through the Li Ka Shing Knowledge Institute of St. Michael's Hospital.

The following PICOS informed the search strategy:

Patients: all obstetrics patients
Interventions: patient safety initiatives
Comparators: compared to each other or no initiative
Outcomes: litigation (number of cases), costs, patient harm (specifically cerebral palsy, shoulder dystocia, non-reassuring fetal status, birth-related neurological injuries)
Studies: randomised clinical trials

Study Selection: Screening

Prior to commencing the screening process, a calibration exercise will be conducted to ensure reliability in correctly selecting articles for inclusion. This will entail screening a random sample of 5% of the included citations by all team members, independently. Eligibility criteria will be modified if low agreement is observed between the reviewers (e.g., percent agreement <90%). Two reviewers will then independently screen the remainder of the search results for inclusion using a pre-defined relevance criteria form for all levels of screening (e.g., title and abstract, full-text review). Discrepancies will be resolved by discussion or the involvement of a third reviewer.

Data Abstraction:

A data abstraction form will be drafted and pilot-tested by all team members independently on a random sample of 10 articles and revised iteratively by the study team while the search is completed. It is anticipated that the data items will include information related to the outcomes of interest. Pairs of team members will independently read each article and extract the relevant data. Differences in abstraction will be resolved by discussion or the involvement of a third reviewer.

Synthesis

We will narratively describe the included randomised clinical trials. If possible, a meta-analysis will be considered after the preliminary report has been submitted to Dr. Sarah Barber and her team of the World Health Organization. We will present the outcome results in tables and categorised by intervention, obstetrical issue, and country of origin.

Appendix B – Quality Improvement (QI) Strategies; Full Definitions

Complex Intervention
Complex interventions are important to resolve the common, complex challenges in health care. Quality improvement strategies are considered complex interventions. Complex interventions require detailed descriptions of the intervention to enable researchers to replicate the study, synthesise the results, and implement findings. However, details of complex interventions are often underreported in research. A falls prevention program for seniors is an example of a complex intervention because it often has more than one interacting component administered within the intervention group. For example, the intervention group may receive exercise training with a physiotherapist (exercise training), the physiotherapist may receive training to administer the program specifically to elderly patients (clinician education), and the patients may receive education about falling (patient education). These interventions are challenging to deliver or receive, target more than one level of organisation (e.g., both the patient and healthcare provider levels), include multiple dosages and formulations, and allow for the tailoring of interventions across settings (e.g., physiotherapist uses slightly different approaches for different patients in the intervention group).

QI strategies targeting health systems		
Case management	Any system for coordinating diagnosis, treatment, or routine management of patients (e.g., arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician. If the study called the intervention "case management" we classified it as such.	Includes nurse phoning regularly to check on patient, nurse calling to promote diet adherence, discharge planning, post-hospital services and home visits
Team changes	Changes to the structure or organisation of the primary health-care team (adding team member, multidisciplinary teams, expansion or revision of professional roles)	Includes multidisciplinary collaboration, appointments with specialists, attending a obstetrics clinic, referrals to specialists or other healthcare providers
Electronic patient registry	General electronic medical record system or electronic tracking. Do not include websites unless patients were tracked over time. To qualify, it had to be a part of the clinical trial as an intervention (i.e., not pre-existing infrastructure unless used more actively)	
Facilitated relay of info to clinicians	Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record (excluding conventional means of correspondence between clinicians.)	
Continuous	Interventions explicitly identified as	

QI	involving the techniques of continuous QI, total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their effects, and then reassessing the need for further action	
QI strategies targeting health-care providers		
Audit & feedback	Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which was then transmitted back to the clinician. This strategy was strictly based on clinical data and excluded clinical skills. It could include the number of patients with missing tests and dropouts.	
Provider education	Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target disorder or population of patients. Includes conferences or workshops, distribution of educational materials (written, video, or other), and educational outreach visits.	Includes staff training, education workshops, seminars, and outreach
Clinician reminders	Paper-based or electronic systems intended to prompt a health professional to recall patient-specific information (e.g., most recent HbA1c value) or to do a specific task (e.g., foot examination).	
Financial incentives	Interventions with positive or negative financial incentives directed at providers (eg, linked to adherence to some process of care or achievement of some target outcome). This strategy also includes positive or negative financial incentives directed at patients or system-wide changes in reimbursement	Includes gym memberships, drug assistance programs, free medications, Rides to the intervention or parking is not included
QI strategies targeting patients		
Promotion of self-management	Provision of equipment or access to resources to promote self-management. If the study called the intervention promotion of self-management, personalised goal-setting, or action-planning, we included it here. We generally thought this a more active strategy than education of patients)	Includes problem-solving skills, tracking the number of steps (fit bit), self-help groups

Patient Reminders	Any effort (e.g., postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. If the intervention included case management, reminders to patients needed to be explicit.	Includes reminder cards, emails, telephone calls
Patient education - written materials, videos, lectures, other	Patient education related to health	Includes pamphlets, booklets/sheets, brochures on safety initiatives, as well as videos, classes, lectures, workshops, other - "instructions" (unspecified) to promote safety
Motivational interviewing	Motivational interviewing ("a directive and client-centered counselling style that relies upon identifying and mobilising the client's intrinsic values and goals to stimulate behaviour change, thus encouraging client and family involvement in all aspects of care.")	Motivational interviewing

Appendix C – Medline Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
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1 Obstetrics/
2 "Obstetrics and Gynecology Department, Hospital"/
3 exp Obstetric Surgical Procedures/
4 obstetric$.tw,hw.
5 exp Obstetric Labor Complications/
6 exp "Dilatation and Curettage"/
7 exp Hysterectomy/
8 Sterilization, Tubal/
9 Salpingostomy/
10 exp Pregnancy Complications/
11 cerebral palsy/
12 Asphyxia Neonatorum/
13 (abortion$ or cervical cerclage or colpotomy or culdoscop$ or fetoscop$ or hysteroscop$ or hysterotomy).tw.
14 (paracervical block$ or obstetric$ anesthe$ or obstetric$ anaesthe$).tw.
15 (Cesarean or Episiotom$ or obstetric$ extraction$ or fetal version).tw.
16 ((induc$ or augmentation or premature or pre-term or preterm or obstructed) adj (labour or labor)).tw.
17 (Abruptio Placentae or breech or Cephalopelvic Disproportion or premature rupture of fetal membrane$ or prom or fetal membranes premature rupture or Dystocia or Uterine Inertia or Chorioamnionitis or Placenta Accreta or Placenta Previa or Postpartum Hemorrhage or Uterine Inversion or Uterine Rupture or Vasa Previa).tw.
18 (Fetal Death or Fetal Resorption or Stillbirth or perinatal death or peri-natal death or Maternal Death or Birth Injuri$ or obstetric$ paralys$).tw.
19 (pre-eclampsia or dilatation or Curettage or Vacuum aspiration).tw.
20 (asphyxia neonatorum or cerebral palsy or birth asphyxia or fetal pulmonary embolism or dystocia or ((birth adj (trauma$ or complication$)) or preeclampsia) or ((birth adj (trauma$ or complication$)) or preeclampsia)).tw.
21 exp Dystocia/ or exp Pregnancy Complications, Cardiovascular/
22 or/1-21
23 (safe$.ti,ab. or exp Safety/ or Err$.ti,ab. or Adverse.ti,ab.) and (exp Risk Management/ or exp Quality of Health Care/ or exp Medical Errors/ or Safety Management/ or Medical Audit/)
24 patient safety/
25 (patient safe$ or obstetric$ safe$).tw.
26 22 and (23 or 24 or 25)
27 case reports.pt.
28 Observational Study.pt.
29 (News or Newspaper Article or comment or editorial).pt.
30 or/27-29
31 randomized controlled trial.pt.

32 (randomized or placebo).mp.
33 clinical trial.pt.
34 or/31-33
35 comparative study.pt.
36 26 and 34
37 limit 36 to english
38 limit 37 to yr=2004-2015
39 38 not 30

Appendix D – Patient and Intervention Characteristics

First Author, Year	Study Design	Study Period	Intervention Provider	Abbreviated Intervention Name	QI Strategy	Intervention Setting	Intervention Setting Description	Sample Size	Duration/ Frequency of intervention
Althabe, 2004[4]	cluster RCT	Oct 1998 - Jun 2000	physicians	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	70,410 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
				Control (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	78,866 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
Riley, 2011[5]	cluster RCT	2005 - 2008	labour and delivery staff	Didactic training with in-situ patient simulations	Provider education	Hospital	small-sized community hospitals (50 beds); rural/suburban in the US	36 medical personnel; 380 births/year	4 months (30 min webinar, 11 in-situ simulations (30-40mins), 2-hour debriefing immediately following each)
				Didactic training only	Provider education	Hospital	small-sized community hospitals (66 beds); rural/suburban in the US	60 medical personnel; 889 births/year	4 months (30min webinar)
				Control (usual care)	usual care	Hospital	small-sized community hospitals (55 beds); rural/suburban	38 staff; 500 births/year	4 months

							in the US		
Chaillet, 2015[6]	cluster RCT	Apr 2008 - Oct 2011	physicians and nurses	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback	Hospital	16 public hospitals in Quebec, Canada	84,227 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
				Control (usual care)	usual care	Hospital	16 public hospitals in Quebec, Canada	100,725 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
Dumont, 2013[7] [CR: Zongo, 2015[8]]	cluster RCT	Sept 2007 - Oct 2011	obstetric teams	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,931 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention (initial 6-day training workshop for healthcare professionals and quarterly educational clinically oriented and evidence-based outreach visits); 1 year post-intervention

				Control (usual care)	usual care	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,236 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention; 1 year post-intervention
Althabe, 2008[9]	cluster RCT	Sept 2003 - Dec 2006	birth attendants	Multifaceted behavioral intervention	Provider education; Clinician reminders	Hospital	public maternity hospitals (9 in Argentina and 1 in Uruguay)	baseline: 2,963 vaginal deliveries; post-intervention: 2,587 vaginal deliveries; 295 birth attendants	intervention: 18 months; post-intervention follow-up: 12 months
				Control (standard in-service training)	Provider education	Hospital	public maternity hospitals (8 in Argentina, 1 in Uruguay)	baseline: 2,503 vaginal deliveries; post-intervention: 2,366 vaginal deliveries; 237 birth attendants	intervention: 18 months; post-intervention follow-up: 12 months
Nielsen, 2007[10]	cluster RCT	Dec 2002 - Mar 2004	clinical staff	Teamwork training (i.e. MedTeams)	Provider education; Team change	Hospital	7 US hospitals (3 military and 4 civilian)	14,200 total deliveries; 1,307 trained personnel	2 month pre-intervention; 3-day training; 5 month post-intervention

				Control (usual care)	usual care	Hospital	8 US hospitals (3 military and 5 civilian)	14,336 total deliveries	2 month pre-intervention; 5 month post-intervention
Horbar, 2004[11]	cluster RCT	May 1999 - Dec 2001	hospital staff	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	Audit and feedback; provider education; team change	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	3,313 newborns	1 year (one time individualised feedback; 2-day workshop; routine reports)
				Control (usual care with centre-specific routine reports)	Audit and feedback	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	2,726 newborns	1 year (routine reports)
Colbourn, 2013[12]	cluster RCT	Jun 2007 - Dec 2010	volunteer facilitators, village women's groups, health centre facility staff	Community mobilisation intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi	Community and Hospital	14 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,249 births	16 months pre-intervention; 27 months intervention
			health centre facility staff	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi	Hospital	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,335 births	16 months pre-intervention; 27 months intervention

			volunteer facilitators, village women's groups	Community mobilisation intervention only	patient education	Community	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,080 births	16 months pre-intervention; 27 months intervention
			NA	Control	usual care	Hospital	17 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	4,912 births	16 months pre-intervention; 27 months intervention
Lumley, 2006[13]	RCT	May 1982 - Dec 1994	midwives	Pre-pregnancy health intervention	Team change; patient education; patient reminders	Community	Maternal and Child Health (MCH) centres, Australia	392 pregnant women who underwent delivery	one home visit for general pregnancy discussion and as needed during pregnancy
				Control (usual care)	usual care	Community	Maternal and Child Health (MCH) centres, Australia	394 pregnant women who underwent delivery	one home visit for general pregnancy discussion
Olds, 2014[14]	RCT	Jun 1990 - Dec 2011	community nurse	Transportation only	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee,	166 pregnant women who underwent delivery	as needed during pregnancy

						US		
			Transportation with screening and referral services	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US	514 pregnant women who underwent delivery	as needed during pregnancy and once post-partum
			Transportation and home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US	230 pregnant women who underwent delivery	as needed during pregnancy and two visits post-partum
			Transportation with screening and referral services, plus home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US	228 pregnant women who underwent delivery	as needed during pregnancy and until child 2 years of age
NA, not applicable; QI, quality improvement; RCT, randomized clinical trials; US, United States								

Appendix E – Intervention descriptions

First Author, Year	Intervention Description	Abbreviated Intervention Name	QI Strategy
Althabe, 2004[4]	**Seminar, Guidelines and Mandatory second opinion:** The intervention consisted of the implementation of a policy of mandatory second opinion at the hospitals assigned to the intervention group. Second opinion was to be sought by the attending physician systematically before caesarean section. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department for this trial, and who had agreed to follow the clinical guidelines. A physician could have the role of attending physician on some days and consultant on others. To assess the clinical case, the consultant followed guidelines prepared as decision flowcharts, for six primary indications for caesarean section. Each guideline had suggestions about how to deal with the problem that originated the indication. Both physicians discussed the case in relation to the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals. NOTE: All decisions to undertake caesarean sections (either elective or intrapartum) in intervention hospitals were eligible for a mandatory second opinion, except if the woman specifically refused to be seen by a second doctor or the situation was an extreme emergency such as maternal haemorrhage, cord prolapse, suspected uterine rupture, or any situation where the attending physician judged that a delay would constitute malpractice.	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	provider education
	Control (seminar only): a formal seminar on pregnancy and delivery care offered to all clinicians prior to randomisation	Control (educational seminar offered to all prior to randomisation)	provider education
Riley, 2011[5]	**Didactic with in-situ simulation:** *Didactic Training:* Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop	Didactic training with in-situ patient simulations	provider education

	communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviours from the didactic training. *In-Situ Simulation:* The in-situ simulation for perinatal critical events consisted of five components: (a) briefing, (b) in-situ simulation, (c) debriefing, (d) rapid-cycle follow-through with process improvements, and (e) repetition to reinforce skills and create resiliency. During the briefing, participants who were directly involved in the simulation were educated about the simulation scenarios. The simulated patient was followed from triage, through labor and the operating room (OR), and then to the recovery area. The simulation, which typically ran 30 to 45 minutes, was initiated in a manner similar to a typical handoff, with a brief history from one provider to the next. A two-hour debriefing session, with the use of advanced debriefing techniques, was held immediately following each simulation. Scenarios and triggers were taken from actual occurrences in the hospital unit. We used an event-set methodology to develop scenarios for uterine rupture, placental abruption, and post-partum haemorrhage. The event sets specified phases for each of the three scenarios. Five clinical triggers were designed to prompt NTS behaviors: situational awareness, shared mental model, closed-loop and SBAR-R29 communication, leadership and teamwork, and latent conditions.		
	Didactic only: Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviors from the didactic training.	Didactic training only	provider education
	Control : no intervention	Control (usual care)	usual care

Chaillet, 2015[6]	**QUARISMA program:** *Selection of opinion leader, audit committee and training* - The first 6 months of the 1.5-year intervention period focused on identifying the opinion leader in each intervention hospital (with the use of surveys) and selecting the local audit committee (which consisted of one or two obstetrician–gynecologists, one or two general practitioners, and one nurse), developing local expertise in conducting audits and providing feedback (1-day training), and improving the performance of health professionals in monitoring indications for cesarean delivery and managing intrapartum care (1-day training). *Audit and Feedback* - During the year after the training period, four 3-month audit cycles were implemented by audit committees, with the support of external facilitators who made quarterly educational outreach visits. Each cycle included five standardised steps: the identification of women who had cesarean deliveries during the first month of each cycle; the collection of data, with the use of standardised forms, regarding the management of labor and delivery; the assessment by the local audit committee, with the use of clinical algorithms, of the relevance of the indications for cesarean delivery; the formulation of recommendations for best practices and the evaluation of previous recommendations, both performed by the committee; and the provision of informal and formal feedback to health professionals.	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback
	Control: No intervention from the QUARISMA team was planned for the control group. In order to assess contamination bias, quality-improvement programs were reviewed annually in control hospitals.	Control (usual care)	usual care
Dumont, 2013[7] [CR: Zongo, 2015[8]]	**ALARM (Advances in Labour and Risk Management) international course for providers:** 3 days of training in best practices in emergency obstetric care, 1 day of training in maternal death reviews, 1 day of awareness training related to economic, socio cultural, and ethical barriers (including sexual and reproductive rights), and 1 day of training in adult education methods. Two recertification sessions (once a year). *Multidisciplinary audit committee* including physicians, midwives, nurses, and administrators was created in each participating site and trained in the process of undertaking maternal death reviews.	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback
	Control: hospitals randomised to the control group did not receive any intervention from the research team. Administrators of these hospitals were informed that the 6-day training workshop would be provided at the end of the trial	Control (usual care)	usual care
Althabe, 2008[9]	**Multifaceted behavioral intervention:** *Selection of opinion leaders* - Teams of three to six birth attendants (physicians, residents, or midwives) were identified as opinion leaders by their peers at each intervention hospital with the use of a previously validated sociometric questionnaire. *Interactive workshops/training of manual skills* - Each team was trained in a 5-day workshop to develop and disseminate evidence-based guidelines on management of the third stage of labor and the use of episiotomy. The workshops focused on critical evaluation of the medical literature, development of clinical practice guidelines,	Multifaceted behavioral intervention	Provider education; Clinician reminders

	communication skills, and methods of conducting one-on-one academic detailing visits with hospital birth attendants to discuss their views regarding implementation of the intervention at the hospital. *Dissemination of training to hospital birth attendants, development of clinician reminders* - After returning to their respective hospitals, the teams participated in 1-day workshops to develop their training skills. The teams then disseminated the guidelines, trained and visited birth attendants, and developed reminders to be placed in labour and delivery wards, inside surgical packages for birth attendants, and on clinical records. *Feedback* - The teams also produced monthly reports on rates of use of episiotomy and prophylactic oxytocin based on hospital clinical data. Regional coordinators met monthly with each team to assess completion of the activities.		
	Control (seminar only): No intervention for the control group, but a seminar was held prior to baseline data collections to ensure all hospitals had similar knowledge at baseline	Control (standard in-service training)	provider education
Nielsen, 2007[10]	**MedTeams Labor & Delivery Team Coordination Course:** teamwork training with principles based on crew resource management and a curriculum used in hospital emergency and obstetric departments. Crew resource management attempts to capitalise on the ability of each crew (team) member to see, analyze, and react to the same situation in ways that reduce the potential for error. Clinical staff from the seven intervention hospitals attended a 3-day instructor training session comprising 4 hours of didactic lessons, video scenarios, and interactive training covering team structure and processes, planning and problem solving, communication, workload management, team skills, and implementation. Conflict resolution strategies were included to provide a means of enhancing team behavior. Teamwork training also included assistance with creation and structure of teams at each intervention hospital. Trainers returned to their respective hospitals to conduct onsite training sessions for staff members from obstetrics, anesthesiology, and nursing and to structure each unit into core work teams made up of those nurses, physicians, and staff in direct contact with patients and coordinating teams composed of immediate supervisors, clinical leaders, and unit resource personnel. In addition, a contingency team, a multidisciplinary group of experienced physicians and nurses drawn from practitioners that are on call during a 24-hour period, were trained to respond in a coordinated way to obstetric emergencies.	Teamwork training (i.e. MedTeams)	Provider education; Team change
	Control: no intervention for the control group	Control (usual care)	usual care
Horbar, 2004[11]	**Multifaceted collaborative quality improvement intervention** *audit and feedback:* hospitals received confidential, individualised feedback from the Vermont Oxford Network including site-specific information and peer comparisons related to the administration and timing of surfactant, and delivery room practice for infants of 23-29 weeks' gestation born in 1998 and 1999; *workshop:* included didactic sessions, facilitated site team exercises, and multi-institutional group exercises designed to promote four key "habits" (change, evidence based practice, systems thinking, and collaborative learning);	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	audit and feedback; provider education; team change

	ongoing support: Collaboration among intervention arm teams was fostered through quarterly conference calls and an email discussion list		
	Control (usual care with centre-specific routine reports): control hospitals received centre-specific, confidential reports routinely prepared for members of the Vermont Oxford Network.	Control (usual care with centre-specific routine reports)	audit and feedback
Colbourn, 2013[12]	**Community mobilization and QI at health centres (FI+CI)** *Community mobilization intervention:* 729 participatory women's groups to mobilise communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritise maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies) *Quality improvement intervention at health centres: c*onsisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia.	Community mobilisation intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi
	Quality improvement intervention at health centres (FI): consisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi
	Community mobilization intervention (CI): 729 participatory women's groups to mobilize communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritise maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies)	Community mobilisation intervention only	patient education
	Control: no community or facilities intervention	Control	usual care

Lumley, 2006[13]	**Pre-pregnancy health intervention:** Women randomised to receive the intervention received a pre-pregnancy health intervention that consisted of: 1. Identification of any current social, health or lifestyle problems. 2. Discussion of timing, planning and preparation for the next pregnancy 3. Offers of referral for any specific problem identified (e.g. to a dietician, relaxation group, physiotherapist, family planning clinic, general practitioner) all available at the Community Health Centre or nearby, or at a local hospital clinic; linkage with appropriate community resources (e.g. language-specific play-group) and networks. 4. Taking a family/genetic history and arranging a referral if necessary. 5. Arranging for rubella immunisation if not immune 6. Discussion of the points summarised on a WAIT, STOP, and GO reminder card. The card was headed Signs to follow before pregnancy, and designed to mimic traffic lights. The card included the name and address of the PPIS and the telephone number.	Pre-pregnancy health intervention	team change; patient education; patient reminders
	Control: All women recruited received a home visit from the PPIS midwife with a discussion of their first pregnancy, labour and birth and the postpartum experience. Any questions asked by the women were answered.	Control	usual care
Olds, 2014[14]	**Transportation only:** Women in treatment 1 were provided free transportation for prenatal care appointments.	Transportation only	usual care
	Transportation with screening and referral services: Women in treatment 2 were provided the transportation for prenatal care and developmental screening and referral services for their children at ages 6, 12, and 24 months.	Transportation with screening and referral services	usual care

	Transportation and home visits: Women in treatment 3 were provided the free transportation and nurse home visits during pregnancy plus 2 postpartum visits. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women's protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.	Transportation and home visits	case management; team change
	Transportation and home visits with screening and referral services: Women in treatment 4 were provided the same services as those in treatment 3, plus home visits through child age 2 years as well as developmental screening and referrals for their children. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women's protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.	Transportation with screening and referral services, plus home visits	case management; team change
QI, quality improvement			

Appendix F – Key outcome definitions by trial

Stillbirths [baby born with no signs of life at or 28 weeks of pregnancy][15]

Althabe 2004[4]	Classified as stillbirths by author, no details provided
Althabe 2008[9]	Classified as stillbirths by author, no details provided
Colbourn[12]	The ICD-10 criteria for stillbirth modified to include births after 28 weeks instead of 22 weeks of pregnancy
Dumont[7]	Classified as stillbirths by author, no details provided
Olds[14]	Classified as stillbirths by author, no details provided

Perinatal mortality [stillbirths with a gestational age of 28 weeks or more and deaths in the first week of life (early neonatal deaths)][16 17]

Althabe 2004[4]	Classified as perinatal mortality by author, no details provided
Colbourn[12]	Death of newborn within first 7 days of life
Lumley[13]	Classified as perinatal mortality by author, no details provided

Neonatal mortality [death of a newborn within the first four weeks of life][17]

Althabe 2004[4]	Classified as neonatal mortality by author, no details provided
Althabe 2008[9]	Classified as neonatal mortality by author, no details provided
Colbourn[12]	Death of newborn within first 28 days of life
Dumont[7]	Death of newborn <24 hours after birth (early) or after the first day of life (late)

Maternal mortality [death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes][18]

Althabe 2004[4]	Classified as maternal mortality by author, no details provided
Althabe 2008[9]	Classified as maternal death by author, no details provided
Colbourn[12]	Death of a woman while pregnant or within 42 days of termination of pregnancy from any cause related to the pregnancy
Chaillet[6]	Classified as maternal death by author, no details provided
Dumont[7]	Classified as hospital-based maternal mortality, no details provided
Olds[14]	Categorized into natural deaths or external deaths. Natural causes in this sample included neoplasms, human immunodeficiency virus infection, sickle cell anemia, diabetes mellitus, endocarditis, stroke, renal disease, acidosis, aortic dissection, and pulmonary embolism. External causes included drug overdose, suicide, unintentional injuries, and homicide.

Caesarean sections [surgical delivery of infants for medically indicated or elective reasons][19]

Althabe 2004[4]	Elective/non-emergency or intrapartum caesarean section
Chaillet[6]	Classified as caesarean delivery, no details provided
Dumont[7]	Elective/non-emergency caesarean sections

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